

PATENT COOPERATION TREATY  
Re PCT/PTO 14 APR 2005  
PCT

REC'D 00 FEB 2005  
WIPO PCT

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>VS:CE FP18624</b>	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. <b>PCT/AU2003/001365</b>	International Filing Date (day/month/year) <b>15 October 2003</b>	Priority Date (day/month/year) <b>16 October 2002</b>
International Patent Classification (IPC) or national classification and IPC <b>Int. Cl. <sup>7</sup> A61K 38/08, 38/12, A61P 29/00</b>		
Applicant <b>THE UNIVERSITY OF QUEENSLAND et al</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

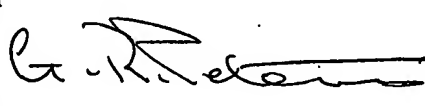
2. This REPORT consists of a total of **3** sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of **4** sheet(s).

3. This report contains indications relating to the following items:

I	<input checked="" type="checkbox"/> Basis of the report
II	<input type="checkbox"/> Priority
III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/> Lack of unity of invention
V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/> Certain documents cited
VII	<input type="checkbox"/> Certain defects in the international application
VIII	<input type="checkbox"/> Certain observations on the international application

Date of submission of the demand <b>14 May 2004</b>	Date of completion of the report <b>21 January 2005</b>
Name and mailing address of the IPEA/AU <b>AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929</b>	Authorized Officer  <b>G.R. PETERS</b> Telephone No. (02) 6283 2184

**I. Basis of the report**

1. With regard to the elements of the international application:\*
- ☐ the international application as originally filed.
- ☒ the description, pages 1-41, as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☒ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages 42-45, received on 14 January 2005 with the letter of the same date.
- ☒ the drawings, pages 1/8-8/8, as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*
- \* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).
- \*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement.**

Novelty (N)	Claims 1-24	YES
	Claims	NO
Inventive step (IS)	Claims	YES
	Claims 1-24	NO
Industrial applicability (IA)	Claims 1-24	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)****Inventive Step (IS) claims 1-24****Citations:**

- 1) WO 1999/000406
- 2) WO 1998/045309
- 3) Current Medicinal Chemistry, 199, 6, pp375-388
- 4) Proceedings of the Society for Experimental Biology and Medicine. 1992, Vol 200, pp 228-232

Claims 1-24 are now limited to the use of the cyclic peptide of formula 1 as the G-protein coupled receptor antagonist used in the treatment of inflammatory bowel disease.

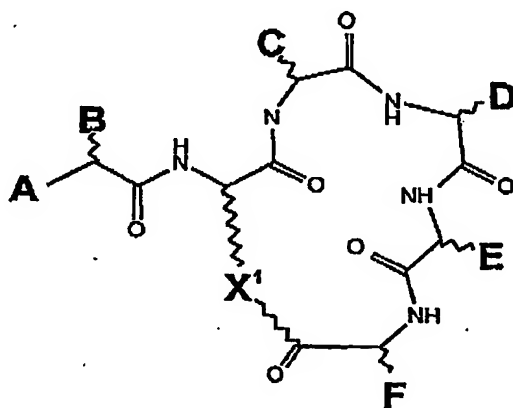
The cyclic peptides are already known from citation 1 that also describes them as G-protein coupled receptor antagonists and as was mentioned previously citations 2-4 all disclose the fact that such antagonists are useful in the treatment of inflammatory bowel disease.

It would have been obvious for the skilled worker to combine citation 1 with either of citations 2-4 and endeavour to treat the said disease with the peptides of formula 1.

Claims 1-24 cannot be considered to involve an inventive step when citation 1 is considered in combination with either or all of citations 2-4 and do not comply with article 33(3) of the PCT.

CLAIMS

1. A method of treatment of inflammatory bowel disease, comprising the step of administering an effective  
5 amount of an inhibitor of a G protein-coupled receptor to a subject in need of such treatment, in which the inhibitor is a compound which
- (a) is an antagonist of a G protein-coupled receptor,  
(b) has substantially no agonist activity, and  
10 (c) is a cyclic peptide or peptidomimetic compound of formula I



- 15 where A is H, alkyl, aryl, NH<sub>2</sub>, NH-alkyl, N(alkyl)<sub>2</sub>, NH-aryl, NH-acyl, NH-benzoyl, NHSO<sub>3</sub>, NHSO<sub>2</sub>-alkyl, NHSO<sub>2</sub>-aryl, OH, O-alkyl, or O-aryl;
- B is an alkyl, aryl, phenyl, benzyl, naphthyl or  
20 indole group, or the side chain of a D- or L-amino acid, but is not the side chain of glycine, D-phenylalanine, L-homophenylalanine, L-tryptophan, L-homotryptophan, L-tyrosine, or L-homotyrosine;
- C is the side chain of a D-, L- or homo-amino  
25 acid, but is not the side chain of isoleucine, phenylalanine, or cyclohexylalanine;
- D is the side chain of a neutral D-amino acid, but is not the side chain of glycine or D-alanine, a bulky planar side chain, or a bulky charged side chain;